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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,561	Applicant(s) CLARK ET AL.	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/1/05</u> | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Election acknowledged

1. Applicants' election with traverse the invention group II of claims 9-15 is acknowledged. The restriction is made without traverse. Therefore, the restriction requirement is deemed to be proper and made FINAL.
2. The elected claims 9-15 are presented for the examination. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected. The following rejections are made.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 8/1/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Pines et al(US 5330974).

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The claims are drawn to a composition comprising a lipid rich component and fibrinogen.

Pines teaches a therapeutically effective fibrinogen composition used as an adhesive or sealant, see abstract. Pines' composition comprising a fibrinogen, protein species(lipid rich layer) and a carrier, see col. 8, lines 30-45.

All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is anticipated and not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al in view of Brown et al and Mosesson et al(1966) and Brown(1993).

Pines' teaching is mentioned in 102 rejection(see above).

Applicant's claims differ in that they require a fibrinogen containing composition where fibrinogen processed by precipitating plasma with glycine.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Brown' teaching to include a further teaching of Clark et al and Mosesson because Mosesson remedy the deficiency of Pines et al.

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Mosesson et al teach a method for the preparation of highly purified human fibrinogen having a clottability of about 98% via repeated precipitation of plasma with glycine(starting materials). Mosesson et al teach reprecipitation with glycine to increase clottability more than 97% and conditions required for processing such precipitation. For instance, the reprecipitation in a buffer, the addition of ammonium sulfate, lipid-proteins, see pages 2833-2834.

Brown et al teach about fibroblast migration where Brown suggests the enhanced fibroblast migration achieved by extensive clotting of said fibrinogen took place in vivo, see abstract. Brown's teaching is supported by measuring factor XIII activity and is tested with contacting highly purified fibrinogen(3mg/ml) that has >95 % of clottability, thrombin and calcium, see page 274," Fibrinogen purification". Brown teaches that highly purified fibrinogen is obtained when the clottability is >98%, where several plasma proteins are separated during the purification process,see figure 2 and column 1 at page 277. Brown also teaches that fibroblast migration is critical factor for the wound healing process wherein fibrinogen clotting(fibrin gel) is gradually replaced by granulation tissue and later by collagenous tissue that is designated by "scar tissue" , see page 273, 2nd column. It is noted that formation of scar tissue is conventionally known as an initial step of wound healing process. Brown also teaches other factors regulating cell migration such as growth factors, see page 273. Furthermore, Brown teaches that fibroblast migration is maximal at the concentration of 3mg/ml, see figure 3 at page 278.

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Although, Pines et al does not mentioned explicitly about the sources and preparation of fibrinogen, one would have been motivated to use fibrinogen obtained by the preparation taught in Mosesson's because it is clearly advantageous to use highly purified fibrinogen to maximize the effectiveness as suggested by these cited references(supra).

Thus, one would have been motivated to use fibrinogen that has been prepared by the precipitation of plasma with glycine because the said preparation including additional purification via repeated precipitation allows the fibrinogen to increase its clottability more than about >95%, preferably > 98%(about 99%) which in turn, would maximize fibroblast migration when it is contacted into wound site in vivo. One would have been motivated to make such modification with reasonable expectation of success because the teaching of each reference together(Pines in view of Mosesson and Brown) provides all the necessary information that suggests the positive outcomes(Clark and Brown) proven via *in vivo* and *in vitro* studies and teaches the sources for highly purified material such as fibrinogen (Mosesson). Since the clottability of fibrinogen(by purification via repeated precipitations) is critical factor for fibroblast migration and heavy clotting would enhance the said migration into the wound site so that one would have been motivated to perform the test without undue burden where the minor modifications required in such test would be conventional and considered to be well within the level of the artisan having ordinary skills.

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The minor variations including the selection of optimal environment and steps in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

Conclusion

3. No claim is allowed.
4. This is 2nd Non-final rejection.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Page Thurman can be reached on 571-272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim,
Patent examiner
October 17, 2005
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